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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,556	01/31/2001	Mitchell Anthony DeLong	79999	4976
23409	7590	12/14/2004	EXAMINER	
MICHAEL BEST & FRIEDRICH, LLP 100 E WISCONSIN AVENUE MILWAUKEE, WI 53202			MITCHELL, GREGORY W	
			ART UNIT	PAPER NUMBER

1617

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 09/774,556	<b>Applicant(s)</b> DELONG ET AL.	
	<b>Examiner</b> Gregory W Mitchell	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11,12,16 and 21-50 is/are pending in the application.
- 4a) Of the above claim(s) 11,12,16,21-25,35,36,40,47 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-34,37-39,41-46,48 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is in response to the response and amendments filed September 27, 2004. Claims 1-10, 13-15, 17-20 and 51 have been cancelled. Claims 11, 12, 16, and 21-50 are pending. Claims 11, 12, 16, 21-25, 35, 36, 40, 47 and 50 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 26-34, 37-39, 41-46, 48 and 49 are examined herein.

### ***Response to Arguments***

Applicant's arguments with respect to claims 26-34, 37-39, 41-46, 48 and 49 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-34, 37-39, 41-46, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnstone (WO 98/33497) in view of De Long et al. (WO 99/50241).

Johnstone teaches the use of prostaglandins (preferably PGA, PGE, or PGF), derivatives or analogues thereof, for the use in stimulating hair growth in animals and treating hair loss (Abstract; p. 1, lines 1-10; p. 7, lines 6-12). Johnstone teaches the prostaglandins in ointments, lotions, solutions, etc. (pp. 27-29). The treatment was taught to be functional in treatment spans

from 5-254 days (p. 23, lines 13-20; p. 24, lines 24-30). A topical cream containing a prostaglandin, propylene glycol (a penetration enhancer), and polysorbate 80 (a thickener) is taught to be applied to the skin once a day (p. 27, lines 22-23). It is also taught by Johnstone that the vasodilator minoxidil is known for the treatment of hair loss (p. 4, lines 14-19). It is also noted that Johnstone teaches that prostaglandins are useful in the treatment of glaucoma and that the promotion of hair growth was discovered thereby, via the growth and thickening of the eye lashes (p. 4, line 31-p.5, line 8; p. 8, line 25-p. 9, line 35).

Johnstone does not specifically teach the PGF analogues of the instant invention or a treatment involving both a prostaglandin and a vasodilator. Johnstone also lacks a specific teaching of a treatment period of between 6 and 12 weeks.

De Long et al. teaches PGF analogues for the treatment of bone disorders and glaucoma (p. 1, first paragraph; p. 3, first two paragraphs). Exemplified is 11-hydroxylamino-17-phenyl-17-trinor-PGF<sub>2a</sub>, wherein W is CH<sub>2</sub>, X is OH, Y is a single bond, p is 2, q is 0, Z is phenyl, R1 is COOH, R5 is H, R6 is H, a is a double bond, and b is a single bond (p. 28, Example 36).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the prostaglandins of Johnstone with a prostaglandin of De Long et al. because (1) Johnstone teaches that PGF and its derivatives and analogs are preferred for the treatment of hair loss; and (2) De Long et al. teaches a PGF analogue. It is noted that the prostaglandins of both Johnstone and De Long are also known to function similarly in treatments, as both are taught to be useful for the treatment of glaucoma. One of ordinary skill in the art would have been motivated to substitute the prostaglandin of Johnstone with the prostaglandin of De Long et al. because an expectation of similar success in treating hair loss (or promoting hair growth).

It would have been obvious to one of ordinary skill in the art to treat hair loss for a period of 6-12 weeks because that time period falls within the range taught to be effective for treating hair loss with prostaglandins by Johnstone. Furthermore, it would have been obvious to one of ordinary skill in the art to combine a prostaglandin with a the vasodilator minoxidil for the treatment of hair loss because it is obvious to combine two compositions taught by the prior art to be individually useful for the same purpose to form a third composition that is to be used for the very same purpose. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

  
ZHENGJUN WANG  
PRIMARY EXAMINER